REMARKS

STATUS OF THE CLAIMS

Claims 1-30 were pending. Claims 6, 7 and 22-28 have been withdrawn from consideration pursuant to an election of species requirement. Applicants note that upon allowance of a generic claim, Applicants will be entitled to consideration of these claims.

Claim 1 has been amended as shown above to make explicit that a cellular immune response is generated. Support for the amendment can be found throughout the specification as filed, for instance on page 12, line 11 to page 13, line 3; the Figures and the Examples. Thus, claims 1-30 are pending as shown above.

35 U.S.C. § 102

Claims 1-5, 8-14, 16-20, 29 and 30 were rejected as allegedly anticipated by U.S. Patent No. 6,110,898 (hereinafter "Malone"). Malone was cited for allegedly disclosing a method of inducing a mucosal immune response as claimed. (Office Action, page 4). In addition, Malone was alleged to inherently disclose presenting an antigenic polynucleotide to dendritic cells and inducing an HLA response. *Id.*

Applicants traverse the rejection and supporting remarks.

As a threshold matter, Applicants note that the claims are (and were) not drawn to methods of inducing a mucosal immune response. Rather, the claims are drawn to methods of inducing an immune response (local and/or systemic) by mucosal administration.

By contrast, and as acknowledged in the Office Action, Malone is directed to methods of inducing a mucosal immune response (see, claim 1 of Malone). Furthermore, Malone defines a "complete" mucosal immune response as one that induces production of secreted IgA alone. *See, e.g.,* col. 2, lines 39-44, emphasis added, stating:

> Production of secreted IgA is a widely accepted surrogate marker for **complete** mucosal immune responses. Efforts to raise sIgA using current polynucleotide vaccination methods have been inconclusive. The pathways by which mucosal immune response can be elicited have not been fully characterized. Mucosal

> antigen presentation can be associated with either immunologic stimulation or induction of tolerance.

Malone then continues on to state that only intranasal administration of a β-gal "antigen" elicited a mucosal immune response (see, col. 19, lines 8-14):

> In general it was found that intranasal inoculation produced secreted mucosal IgA, but not systemic IgA; whereas the other treatment routes resulted in systemic IgA, but not mucosal IgA, showing that polynucleotide vaccine antigens must be expressed in mucosal tissues adjacent to mucosal associated lymphoid tissue, such as is found at the base of the nares in mice.

Simply put, Malone does not describe generation of immune responses generally, as claimed. Rather, Malone relates the narrower proposition of inducing a mucosal immune response. Moreover, Malone teaches that mucosal immune responses must be humoral sIgA responses, and, in addition, that only intranasal administration results in such responses. Thus, Malone does not teach generation of a cellular immune response, as set forth in the pending claims.

Nor does Malone inherently disclose methods of generating a cellular immune response, as claimed. It is well established that in order to inherently anticipate the subject matter of the claim, the allegedly inherent feature must necessarily and in all cases flow from the disclosure. *See, e.g., Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990). Inherency cannot be established by probabilities or possibilities -- the missing descriptive material must be "necessarily present," not merely probably or possibly present, in the cited art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)); *see, also Continental Ca Co. USA, Inc. v. Monsanto Co.* 20 USPQ2d 1746, 1749 (Fed. Cir. 1987).

In the pending case, Malone teaches that only humoral immune responses are generated upon administration of β-gal "antigen." Moreover, there is no teaching in this reference regarding whether cellular immune responses are generated and, certainly, no disclosure teaching that administration of β-gal antigens would necessarily and in all cases generate a cellular immune response, as claimed.

Thus, Malone cannot expressly or inherently anticipate any of the pending claims and withdrawal of this rejection is in order.

35 U.S.C. § 103

Claim 15 was rejected as allegedly obvious over Malone in view of U.S. Patent No. 6.261,570 (hereinafter "Parker"). (Office Action, page 5). Malone was cited as above and Parker was cited for allegedly disclosing "vaccines directed against numerous alphavirus pathogens....and expressing antigens of other alphaviruses..." *Id.*

For the reasons noted above, Malone does not teach or suggest generating a cellular immune response, as claimed. With regard to claim 15 in particular, Malone is entirely silent as to using a "chimeric" alphavirus vector. For its part, and as acknowledged by the Office, Parker relates to live attenuated alphavirus vaccines, not to alphavirus vectors, as claimed. Unlike Parker, in which the alphavirus serves as both the vector and antigen, the pending claims are directed to methods in which the antigen is heterologous to the vector (see, e.g., page 23, lines 19-20).

Thus, there is no combination of Malone with Parker that can render pending claim 15 obvious and withdrawal of this rejection in order.

CONCLUSION

In view of the foregoing amendments, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §1.16, §1.17, and §1.21, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648, referencing Atty. Docket No. 2302-1631.20.

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